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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,215	02/25/2004	Hugh S. West JR.	14000.8.1.2	3044
7590	02/05/2008		EXAMINER	
John M. Guynn WORKMAN, NYDEGGER & SEELEY 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111			CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	
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				PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/786,215	WEST ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	JERRY CUMBERLEDGE	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 November 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 25 February 2004 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims state that the attaching means (or post) are attached to only one side of the pulley wheel. However, the drawings show a unitary apparatus, wherein the components are all attached to one another.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US Pat. 4,950,271) in view of Fletcher (US Pat. 3,869,932) in view of Bull et al. (US Pat. 4,529,147).

Lewis et al. disclose a suture pulley assembly for use in a graft tensioning device adapted so as to receive one or more looped sutures of varying size and equalize tension on both sides of the looped sutures (Fig. 2, ref. 50), the suture pulley assembly comprising: a rotatable pulley wheel (Fig. 2, ref. 57) (column 5, lines 58-61) comprising first (Fig. 1, left side of ref. 57) and second pulley plates (Fig. 1, right side of ref. 57); attaching means (Fig. 2, unlabeled post through ref. 57) for rotatably attaching said pulley wheel to an adjustable tension applicator of the graft tensioning device (Fig. 2, ref. 57)(column 5, lines 58-61), said pulley plates of said pulley wheel thereby rotating independently of the adjustable tension applicator when equalizing tension between each side of a looped suture. The attachment means comprising a post (Fig. 2, post through ref. 57) that passes through a central recess of each pulley plate and that is attached at a first end to the adjustable tension applicator of the graft tensioning device. The post is fixedly attached to the adjustable tension applicator (Fig. 2). The post further comprising a flange at a second end opposite said first end and adjacent to one of said pulley plates, said flange overlapping at least a portion of an outer surface of said pulley plate adjacent to said flange (Fig. 2, ref. 56). A graft tensioning device (Fig. 1, ref. 40) for use in joint repair surgery, comprising a suture pulley assembly as defined in claim 1 (Fig. 2, ref. 50); and at least one adjustable tension applicator (column 6, lines 51-60) to which said suture pulley wheel of said suture pulley assembly is rotatably attached (Fig. 2, ref. 57)(column 5, lines 58-61) and which is configured to move together with said adjustable tension applicator in order to transmit a desired tensile load from said adjustable tension applicator through said suture pulley assembly to a looped suture

wrapped around said pulley wheel within said pulley wheel within said pulley space and attached to free ends of a looped tissue graft (Fig. 2), said suture pulley assembly being adapted for equalizing a tensile load applied by said adjustable tension applicator to each side of the looped suture. The graft tensioning device comprising two independently adjustable tension applicators (Fig. 2, refs. 50) and a separate suture pulley (Fig. 2, central ref. 50) assembly as defined in claim 1 rotatably attached to each of said two independently adjustable tension applicators (Fig. 2).

Lewis et al. disclose, in a graft tensioning device for use in joint repair surgery, a suture pulley assembly (Fig. 2, ref. 50) adapted so as to receive one or more looped sutures of varying size and equalize tension on both sides of the looped sutures, the suture pulley assembly comprising: a rotatable pulley wheel (Fig. 2, ref. 57)(column 5, lines 58-61) comprising first (Fig. 1, left side of ref. 57) and second pulley plates (Fig. 1, right side of ref. 57). The first and second pulley plates having inner surfaces that define said pulley space (Fig. 2, place where ref. 57 sits). The post is fixedly attached to the adjustable tension applicator (Fig. 2). The post further comprising a flange (Fig. 2, ref. 56) at a second end opposite said first end and adjacent to one of said pulley plates, said flange overlapping at least a portion of an outer surface of said pulley plate adjacent to said flange.

Lewis et al. disclose a graft tensioning device for use in joint repair surgery, comprising: at least one adjustable tension applicator (Fig. 2, ref. 40) configured to apply varying tensile loads to a looped suture attached to free ends of a looped tissue graft; and a suture pulley assembly (Fig. 2, ref. 50) attached to said adjustable tension

applicator and movable together with said adjustable tension applicator so as to transmit varying tensile loads from said adjustable tension applicator to the looped suture as said adjustable tension applicator is moved relative to the looped structure (Fig. 2), said suture pulley assembly comprising: a pulley wheel (Fig. 2, ref. 57)(column 5, lines 58-61) rotatably attached to said adjustable tension applicator and comprising first (Fig. 1, left side of ref. 57) and second pulley plates (Fig. 1, right side of ref. 57), a post (Fig. 2, unlabeled post through ref. 57) attached at a first end to said adjustable tension applicator, said post passing through a central recess of each of said first and second pulley plates so as to rotatably (column 5, lines 58-61) attach said pulley wheel to said adjustable tension applicator and allow said pulley plates to rotate independently of said adjustable tension applicator when equalizing tension between each side of a looped suture.

Lewis et al. disclose the claimed invention except for only one side of the pulley wheel being attached to an adjustable tension applicator so that an outer periphery of each of the first and second pulley plates and also said pulley space remain entirely unobstructed by any structure of the graft tensioning device in order to provide free and unobstructed access of a looped suture with no free end around said pulley wheel within said pulley space; a second end of the post opposite said first end remaining unattached to any portion of the adjustable tension applicator; the flange remaining unattached to any portion of the adjustable tension applicator so as to not obstruct said outer perimeter of each of said first and second pulley plates or said pulley space. Lewis

et al. disclose the pulley wheel as being used to hold and guide a strand of material (a ligament graft) (Fig. 2)(column 5, lines 56-61).

Bull et al. disclose a device (Fig. 2) comprising a pulley (Fig. 2, ref. 77) which comprises a pulley wheel (Fig. 2, wheel of ref. 72) which is attached to only one side of an attaching means (Fig. 2, ref. 42) with a pulley space (Fig. 2) and an outer perimeter that are entirely unobstructed by any portion of the rest of the device (Fig. 2). The post and flange are attached to one side of the wheel (Fig. 2). The pulley is used to hold and guide a strand of material (Fig. 2)(column 5, lines 4-8).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the pulley and attachment means of Lewis et al. with the pulley and attachment means as taught by Bull et al., in order to achieve the predictable result of allowing the pulley to hold and guide a strand of material.

Lewis et al. in view of Bull et al. do not disclose the pulley plates having a variable distance therebetween which sized and positioned so as to define a variable pulley space for accepting therein at least one looped suture; and biasing means for biasing at least one of said pulley plates toward the other of said pulley plates with a biasing force in order for said pulley space defined by the distance between said first and second pulley plates to selectively increase or decrease in cross-sectional width as the distance between said pulley plates increases or decreases in response to insertion of differently sized sutures into said pulley space; a spring positioned relative to at least one of said first and second pulley plates so as to bias at least one of said pulley plates toward the other of said pulley plates in order for said pulley space defined by said

distance between said first and second pulley plates to selectively increase or decrease in cross-sectional width as the distance between said pulley plates increases or decreases in response to insertion of differently sized sutures into said pulley space; at least a portion of said inner surfaces of said first and second pulley plates being angled so that at least a portion of said pulley space has decreasing width from an outer perimeter of said pulley plates toward a center of said pulley wheel; only a portion of said inner surfaces of said first and second pulley planes being angled so that only a portion of said pulley space has decreasing width from said outer perimeter of each said pulley plates and so that a portion of said pulley space nearest said center of said pulley wheel having a constant width. The suture assembly further comprising a sleeve disposed around at least a portion of said post between said post and an inner edge of each pulley plate defining said central recess. The spring being disposed around a portion of said sleeve. The suture pulley assembly further comprises a washer disposed between said spring and the adjustable tension applicator of the graft tensioning device. Lewis discloses that having a more precise and repeatable length adjustment of the ligament graft or graft components is desirous (abstract).

Fletcher discloses a pulley wheel (Fig. 1) with two pulley plates (Fig. 1, refs. D and E) having a variable distance therebetween (column 1, lines 15-19) which is sized and positioned so as to define a variable pulley space; a biasing means (column 1, lines 19-22, e.g. the leaf springs); the spring at least a portion of said inner surfaces of said first and second pulley plates being angled (Fig. 1, angled surfaces of refs. 60 and 62); a spring (column 1, lines 19-22, e.g. the leaf springs) positioned relative to at least one

of said first and second pulley plates so as to bias at least one of said pulley plates toward the other of said pulley plates in order for said pulley space defined by said distance between said first and second pulley plates to selectively increase or decrease in cross-sectional width (column 1, lines 19-22). A portion of said pulley space nearest said center of said pulley wheel having a constant width (Fig. 1, portion near refs. 50 and 52). The device includes a sleeve (Fig. 1, ref. B) and a washer (Fig. 1, ref. 24). This type of pulley wheel allows for the varying of the drive ratio (column 1, lines 19-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the pulley wheel of Lewis et al. in view of Bull et al. having a variable distance between the pulley plates and utilizing a spring as a biasing means as taught by Fletcher in order to allow the device of Lewis et al. in view of Bull et al. to vary the drive ratio (column 1, lines 19-22), in order to realize the predictable result of allowing a surgeon to more precisely and repeatably adjust the length and tension of a graft. By altering the drive ratio of the pulley wheel of Lewis et al. the surgeon would be better able to have a more precise and repeatable length adjustment of the ligament graft or graft component. For example, if a surgeon needed to substantially adjust the length of the ligament, the drive ratio could be altered to allow a small turn of the wheel to effect a large change in the length and tension of the ligament. If a very small, very precise change in length and tension is required, the surgeon would be able to adjust the drive ratio so that a small turn of the wheel would effect a small change in the length and tension of the graft.

Claims 5, 6, and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (US Pat. 4,950,271) in view of Fletcher (US Pat. 3,869,932) in view of Bull et al. (US Pat. 4,529,147) in view of McKee (US Pat. 3,718,129).

Lewis et al. in view of Fletcher in view of Bull et al. disclose the claimed invention except for the spring being a coil spring and the spring being axially disposed around a portion of the post. Lewis et al. in view of Fletcher in view of Bull et al. do disclose that there is leaf spring (column 1, lines 19-22, e.g. the leaf springs) used to bias the plates (column 1, lines 19-22).

McKee discloses a device (Fig. 1) that comprises a pulley (Fig. 4, ref. 11) that comprises a coiled spring (Fig. 4, ref. 143) around a post (Fig. 4, ref. 133). The spring is used to bias plates of the device (Fig. 4)(Fig. 5)(column 8, lines 41-50).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the leaf springs of Lewis et al. in view of Fletcher in view of Bull et al. with a coiled spring around a post as taught by McKee, in order to achieve the predictable result of using a spring to bias plates of the pulley.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

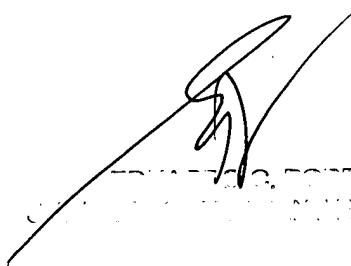
Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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